

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2073817	(X3) Date Survey Completed 03/07/2023
Name of Provider or Supplier Amg Medical Pllc	Street Address, City, State 840 E Mount Hope Avenue, Lansing, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with Technical Consultant #2, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to ensure controls used in urine toxicology testing were not used beyond their expiration date. Refer to D5417.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with Technical Consultant #2, the laboratory failed to ensure controls used in urine toxicology testing were not used beyond their expiration date for 1 of 8 reagents observed. Findings include: 1. The surveyor observed during a tour of the laboratory on 3/07/2023 at 8:52 am, the Buprenorphine controls in the Magic Chef refrigerator with an expiration date of 1/31/2023. 2. When</p>

queried on 3/07/2023 at 10:30 am, Technical Consultant #2 reviewed the patient testing logs to find that 62 patients had toxicology testing with Buprenorphine results on 3/01/2023. 3. An interview on 3/07/2023 at 10:30 am, Technical Consultant #2 confirmed the Buprenorphine controls were expired and had been used in urine toxicology testing beyond their expiration date.